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Richard E. Fichter
BACON & THOMAS, PLLC
Fourth Floor
625 Slaters Lane
Alexandria, VA 22314

EXAMINER	
WANG, SHENGJUN	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/839,366
Filing Date: April 23, 2001
Appellant(s): ETIENNE, MARIE-CHRISTINE

Richard E. Fichter
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the Remand by the Board of Patent Appeals and Interferences issued November 22, 2005.

Pursuant to the remand under 37 CFR 41.50(a)(1) by the Board of Patent Appeals and Interferences on November 22, 2005 **for further consideration of a rejection**, a supplemental Examiner's Answer under 37 CFR 41.50(a)(2) is set forth below:

A) All the rejections and arguments presented in the examiner's answers mailed August 26, 2004 are maintained herein, and additional rejections and remarks are added as follow;

Claim Rejections 35 U.S.C. 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to:

A method for causing the elimination of an active principle, R, from cells of a mammal which contain the active principle, R, which comprises administering to said mammal, a compound identical in nature to said active principal in a homeopathic product of the formula RxCH, in which R is the active principle and in which xCH is a homeopathic dilution of said active ingredient R to eliminate R from the cells to restore normal function to the perturbed pericellular transport systems.

The disclosure teaches that:

The metabolic diseases to which the invention relates are diseases characterized by the intracellular accumulation or intracellular deficit of a chemical substance of simple or complex formula, which can vary from case to case and is designated here by R.

In fact, R acts on pericellular transport systems with respect to itself, which systems have broken down and to which it restores correct function. These diseases are frequently referred to as genetic in the prior art.

Specification, page 2.

The disclosure further teaches that R can be, in the case of cystic fibrosis, without limitation, NaCl, see id. at 6; in the case of pigmentary retinopathy, R may be melanin or sepia, see id.; in the case of oxalosis, R may be oxalic acid or calcium oxalate, see id.; in the case of hyperkalemic periodic paralysis, R may be potassium or a potassium salt, see id. at 6-7; in the case of hemochromatosis, R may be iron, see id. at 7; in the case of Wilson's disease, R may be copper, see id.; in the case of Alzheimer's disease, R may be aluminum or an aluminum salt, see id.; in the case of tetany, R may be dimagnesium phosphate, tricalcium phosphate, or other salts or chemical substances see id. at 7-8; in the case of vitamin-resistant rickets, R may be calcium or mineral salts derived from calcium Calcarea carbonica, oyster limestone, or tricalcium phosphate, see id. at 8; in the case of anemia, R may be iron, see id.; in the case of rheumatoid polyarthritis, R may be black antimony sulfide in the juvenile case, and for the adult case, fluoric acid and graphites, see id. at 9; in the case systemic lupus erythermatosus, R may be gold, see id.; in the case of amyotrophic lateral sclerosis, R may be phosphorus or a phosphorus salt, see id.; in the case of multiple sclerosis, R may be a salt derived from phosphorus, such as calearea phosphorica with another salt, causticum, see id.; in the case of hyperthyroidism, R may be sodium chloride (NaCl), see id. at 9-10.

The specification teaches further that:

Finally, the following complaints may be mentioned as other examples of metabolic diseases, without implying a limitation: Refsum's disease, or R can be phytanic acid, Charcot-Marie-Tooth and Dejerine-Sottas disease, Huntington's chorea, where R can be zinc, Thevenard's disease, Friedrich's disease, Pierre Marie's hereditary cerebellar ataxia, Strumpell Lorrain's

periodic paralysis, Roussy-Levys syndrome, dyslipidosis, idiopathic mental retardation [] in children, and autism.
Id. at 10.

Thus, as can be seen from the above portions of the disclosure, R can be almost anything, and be used to treat almost any complaint. The disclosure does not set forth any functional or structural relationship between what may be used as R and the abnormalities that may be treated. Since the claims read on treating essentially any diseases and/or abnormalities, and since the application fails to set forth any functional or structural relationship between what may be used as R and the diseases and/or abnormalities that may be treated, a skilled artisan would have reasonable doubt that appellants has possession of the Rs beyond the particular examples provided in the application.

In Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002), the Federal Circuit adopted a portion of the Guidelines proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

> The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics."

Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613 (citing Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description Requirement, 66 Fed. Reg. 1099, 1 106 (January 5, 2001)).

In. Universitv of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886, (Fed. Cir. 2004) the Court of Appeals for the Federal Circuit held that claims drawn to methods of inhibiting PGHS-2 activity by administering a non-steroidal compound that inhibits activity of

prostaglandin H synthase-2 were invalid for failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph. See 358 F.2d at 917-18, 69 USPQ2d at 1887-88.

The University of Rochester court made clear that cases such as Enzo do not apply only to claims to genetic material, as the written description requirement applies to all types of inventions. See 358 F.2d at 925, 69 USPQ2d at 1893-94. Moreover, while disclosure of a DNA sequence may support claims to complementary molecules that can hybridize to it due to the complementarity of genetic material, "[t]he same is not necessarily true of the chemical arts more generally." See id. Thus, "[a] description of what a material does, rather that of what it is, normally does not suffice." (citation omitted). See 358 F.2d at 923, 69 USPQ2d at 1892.

In instant case, the application provides a description what the R recited in the claims does, rather that of what it is, and fails to set forth any functional or structural relationship between the function of R and the actual chemical structure of R. Thus, the application fails to comply with the written description requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 22 provides for the application of homeopathic compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Claim 21 reads as a "use" claims, wherein the term "application " has been substituted for the term "use." Claim 21 is not drawn to a composition, no is it drawn to a process. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 21 and 22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

B) Modifying "Prior Art of Record" in the Examiner's Answer mailed August 26, 2004 by adding following prior art:

Labrecque et al. 'Homeopathic treatment of plantar warts,' Can. Med. ASSOC. J. 1992, vol. 146, No. 10, pages 1749-1753.

The appellant must within **TWO MONTHS** from the date of the supplemental examiner's answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the rejection for which the Board has remanded the proceeding:

(1) **Reopen prosecution.** Request that prosecution be reopened before the examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit, or other evidence. Any amendment, affidavit, or other evidence must be relevant to the issues set forth in the remand or raised in the supplemental examiner's answer. Any request that prosecution be reopened will be treated as a request to withdraw the appeal. See 37 CFR 41.50(a)(2)(i).

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. If such a reply brief is accompanied by any amendment, affidavit or

other evidence, it shall be treated as a request that prosecution be reopened under 37 CFR 41.50(a)(2)(i). See 37 CFR 41.50(a)(2)(ii).

Extensions of time under 37 CFR 1.136(a) are not applicable to the **TWO MONTH** time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully Submitted,

SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
AU 1617

SAN-MING HUI
PRIMARY EXAMINER

SUPERVISORY PATENT EXAMINER

A Technology Center Director or designee has approved this supplemental examiner's answer by signing below:

BRUCE KISLIUK, DIRECTOR
TECHNOLOGY CENTER 1600